UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA, Plaintiff,	)	
	)	Civil Action No.
v.	)	
	)	Jury Trial Demanded
PARK SQUARE URGENT CARE, INC.; PRIMACARE, INC.; BILTMORE MEDICAL; BILTMORE MEDICAL A; ADVANCED URGENT CARE; RHODE ISLAND HEALTH GROUP, LLC; AND ZAHEER SHAH, M.D., Defendants.	)	

COMPLAINT

The United States of America ("United States"), by and through its attorney, Aaron L. Weisman, alleges the following:

INTRODUCTION

1. The United States brings this action against Defendants pursuant to the False Claims Act, 31 U.S.C. § 3729, *et seq*. ("FCA"), seeking treble damages and civil penalties, and under common law and equitable theories of recovery.

2. From 2014 to 2015, Park Square Urgent Care, Inc. and its affiliated entities, under the direction of Dr. Zaheer Shah, submitted tens of thousands of false claims to Medicare and Medicaid, seeking reimbursement for urine drug tests that they did not, and could not, perform, based on the capabilities of their laboratory.

3. Specifically, these Defendants knowingly billed the government for the performance of "high complexity" and quantitative urine drug tests purportedly provided for Medicare and

Medicaid beneficiaries, when, in fact, only moderate complexity urine drug screen panels were performed that produced qualitative or semi-quantitative results.

4. Medicare and Medicaid paid a higher reimbursement rate for the performance of high complexity tests than for moderate complexity tests.

5. For most urine drug screens it performed, the laboratory at Park Square Urgent Care first ran a moderate complexity urine drug screen, billed Medicare or Medicaid for a high complexity urine drug test, and then sent the urine specimen to an outside confirmation testing laboratory in order to obtain high complexity test results, allowing the outside confirmation testing laboratory to also bill Medicare or Medicaid for high complexity testing on the same urine specimen.

6. From 2014 to 2015, Park Square Urgent Care and its affiliates received over $1,500,000.00 in payments from the government for high complexity and quantitative tests that they did not perform.

7. These payments were the result of claims that Park Square Urgent Care and its affiliates submitted to the government for tests that Park Square Urgent Care knew were false.

8. Park Square Urgent Care's claims to the government for reimbursement for high complexity and quantitative testing were false claims within the meaning of the False Claims Act, and all of the Defendants have been unjustly enriched by payments made by the government as a result of these false claims.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

10. This Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because each Defendant resided and/or transacted business in the District of Rhode Island during the relevant time period.

11. Venue is proper in the District of Rhode Island under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b), because Defendants transact or transacted business in this District, and a substantial part of the events giving rise to this action occurred in this District.

PARTIES

12. Plaintiff, the United States, acting through the Department of Health and Human Services ("HHS"), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, ("Medicare"), and Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, ("Medicaid").

13. Defendant Park Square Urgent Care, Inc. ("Park Square") is a Rhode Island professional corporation and medical provider located at 63/65 Eddie Dowling Highway, North Smithfield, Rhode Island. Park Square includes an on-site laboratory ("Park Square Laboratory").

14. Defendant PrimaCare, Inc. ("PrimaCare") is a Rhode Island professional corporation and medical provider located at 63/65 Eddie Dowling Highway, North Smithfield, Rhode Island.

15. Defendants Biltmore Medical, Biltmore Medical A, and Advanced Urgent Care are entities through which Park Square Urgent Care, Inc. and/or PrimaCare Inc. have conducted business in Rhode Island. These entities have been located at 63/65 Eddie Dowling Highway in North Smithfield, Rhode Island; 73 Eddie Dowling Highway in North Smithfield, Rhode Island; and 100 Smithfield Avenue in Pawtucket, Rhode Island.

16. Defendant Rhode Island Health Group, LLC is a Rhode Island limited liability company located at 63 Eddie Dowling Highway, North Smithfield, Rhode Island. Since August 2018, Rhode Island Health Group, LLC has owned the non-medical assets of Park Square Urgent Care, Inc. and PrimaCare, Inc.

17. Zaheer Shah, M.D. is a physician who resides in Arizona and is the sole owner of the medical assets of Park Square Urgent Care, Inc. and PrimaCare, Inc.; the President of Park Square Urgent Care, Inc.; and the Chief Executive Officer of PrimaCare, Inc. Dr. Shah is also the Laboratory Director of Park Square Laboratory. Dr. Shah is also a 5% owner of Rhode Island Health Group, LLC.

LEGAL BACKGROUND

I. The False Claims Act

18. The FCA prohibits knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the United States government and for knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims paid by the United States.

19. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A) [or] (B)…

is liable to the United States for three times the amount of damages which the government sustains, plus a civil penalty per violation. For violations occurring between September 28, 1999 and November 2, 2015, the civil penalty amounts range from a minimum of $5,500 to a

maximum of $11,000 per claim. See 28 C.F.R. § 85.3(a)(9) (1999). For violations occurring after November 2, 2015, the civil penalty amounts range from a minimum of $11,181 to a maximum of $22,363 per claim. See 28 C.F.R. § 85.5.

20. For purposes of the FCA, the terms "knowing" and "knowingly" (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. 31 U.S.C. § 3729(b)(1).

21. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

II. The Medicare and Medicaid Programs

22. In 1965, Congress created the Medicare program to pay for the costs of certain health care services. See 42 U.S.C. §§ 1395, *et seq.* HHS, through the Centers for Medicare & Medicaid Services ("CMS"), is responsible for administering and supervising the Medicare program.

23. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries."

24. The Medicare program consists of four parts: A, B, C, and D. Part B covers outpatient care, including physician services and ancillary services, furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k.

A. The Medicare Part B Program

25. Medicare Part B pays for covered clinical diagnostic laboratory tests that are furnished by a laboratory. See 42 C.F.R. §§ 414.500 *et seq*.

26. Medicare Part B only covers laboratory services that are actually provided to Medicare beneficiaries and are medically necessary. See 42 C.F.R. § 411.15(k).

27. HHS provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public on the internet. See generally, CMS Internet-Only Manuals (IOMs), available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html (last visited February 27, 2020) ("CMS Manuals").

28. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

29. To participate in the Medicare program as a new enrollee, group practices and clinical laboratories must submit a Medicare Enrollment Application, Form CMS-855B.

30. Form CMS 855B requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier…I understand that payment of a claim by Medicare is conditioned upon the claim and underlying transaction complying with such laws, regulations, and program instructions…and on the supplier's compliance with all applicable conditions of participation in Medicare.
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> ***
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf (last visited February 27, 2020).

31. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to the laws, regulations, and program instructions of the Medicare program." Id.

32. Park Square has been enrolled in the Medicare program since 2005.

33. On May 23, 2016, Park Square submitted an application to revalidate its enrollment in the Medicare program, which included further acknowledgement that Park Square was bound to the laws, regulations, and program instructions of the Medicare program. This form was signed by Dr. Shah.

34. The National Provider Identifier ("NPI") is a standard and unique health identifier for healthcare providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

35. Park Square's NPI number (also used by Biltmore Medical) is 1366506008, PrimaCare's NPI number is 1841354487, Advanced Urgent Care's NPI number is 1699059741, and Dr. Shah's NPI number is 1962592410.

36. Typically, laboratories are compensated for the services they provide for Medicare beneficiaries on a fee-for-services basis as determined by Medicare's Clinical Laboratory Fee Schedule, which is updated annually. See Clinical Laboratory Fee Schedule, CMS, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files (last visited February 27, 2020).

37. To obtain Medicare or Medicaid reimbursement for clinical laboratory services, providers submit a claim form known as the CMS 1500 form or its electronic equivalent. Among the information the provider or supplier includes on a CMS 1500 form, or its electronic equivalent,

are certain five-digit codes, including CPT ("Current Procedural Terminology") codes and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the services rendered and for which reimbursement is sought, and the NPI of the "rendering provider" and the "referring provider or other source."

38. When enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful." They further acknowledge that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare or Section 1011 program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf (last visited January 27, 2020).

39. By statute, healthcare providers who knowingly present or cause to be presented claims for items or services that a person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent, can be excluded from Medicare, Medicaid, and all other Federal health care programs. See 42 U.S.C. § 1320a-7a(a)(1); 1320a-7(b)(7).

40. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. See Heckler v. Cmty. Health Servs. Of Crawford Cty., Inc., 467 U.S. 51, 64 (1984).

41. Because it is not feasible for the Medicare program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

42. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the above certifications, without any review of supporting documentation, including medical records.

43. During all times relevant to the Complaint, Dr. Shah and Park Square and its affiliated entities were in the business of providing medical services to Medicare beneficiaries and receiving payment for these medical services from Medicare.

44. During all times relevant to the Complaint, Dr. Shah, Park Square and its affiliates billed Medicare Part B for laboratory testing services purportedly furnished by Park Square Laboratory by submitting claims for reimbursement to CMS, either directly or through a medical billing company called Paramount Medical Billing LLC.

45. According to the Rhode Island Secretary of State website, Paramount Medical Billing, LLC was located at 117 Eddie Dowling Highway, North Smithfield, Rhode Island, and was owned by Christine Shah. Christine Shah is Dr. Shah's wife.

46. According to the Rhode Island Secretary of State website, Paramount Medical Billing's certificate of organization/registration to transact business in the State of Rhode Island was revoked in July of 2018. However, the Arizona Corporations Commission, which maintains the corporations database for the state of Arizona, lists Paramount Medical Billing as an active entity owned by Christine Shah.

B. Rhode Island Medicaid Program

47. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups, including the poor and disabled. The state of Rhode Island implements its Medicaid program pursuant to a state plan approved under Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq*.

48. Medicaid in the State of Rhode Island is administered by the Rhode Island Executive Office of Health and Human Services.

49. Within broad federal rules, Rhode Island Medicaid decides eligibility, the services covered, payment levels for services, and administrative and operational procedures. Rhode Island Medicaid directly pays providers and obtains the federal share of the payment from United States Treasury funds. During all times relevant to this Complaint, the United States provided funds to the State of Rhode Island through the Medicaid Program.

50. Enrolled healthcare providers for Medicaid beneficiaries in the State of Rhode Island are eligible for reimbursement for covered services under the provisions of the State of Rhode Island Medicaid statute, R.I. Gen. L. Chapters 40-8, 42-7.2.

51. Under 210 R.I. Code R. § 20-00-1.5, a Rhode Island Medicaid provider is required to comply with all federal and Rhode Island statutes and regulations pertaining to Medicaid.

52. During all times relevant to this Complaint, Dr. Shah and Park Square and its affiliated entities were in the business of providing medical services to Medicaid recipients and receiving payment for these medical services from Rhode Island Medicaid.

III. Urine Drug Testing Overview

A. Regulatory Requirements for Laboratory Test Services

53. The Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, give authority to HHS to regulate all laboratories that examine human specimens for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition, as set forth at 42 C.F.R. Part 493. See also Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15, § 80.1, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (last visited February 27, 2020).

54. The purpose of the CLIA program is to assure that laboratories testing specimens consistently provide accurate procedures and services.

55. CLIA requires that virtually all laboratories meet applicable federal requirements and have a CLIA certificate in order to receive reimbursement from federal programs. Medicare Claims Processing Manual, Ch. 16, § 70.1, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16pdf.pdf (last visited February 27, 2020).

56. Depending on the type of tests that an individual laboratory is capable of performing, multiple types of CLIA certificates may be obtained.

57. Laboratory tests are categorized as one of the following for purposes of CLIA certification: (1) waived tests, (2) tests of moderate complexity, and (3) tests of high complexity. 42 C.F.R. § 493.5(a).

58. Waived tests are simple laboratory examinations and procedures, such as urine cup tests, also known as "quick cups," that carry an insignificant risk of erroneous result, and are exempt from virtually all CLIA rules, so long as testing is performed in compliance with all of the manufacturer's instructions. 42 C.F.R. § 493.15.

59. A certificate of waiver means that a laboratory may only perform certain CLIA-waived tests that are listed in the applicable regulations. 42 C.F.R. § 493.2.

60. In order to perform moderate or high complexity laboratory testing, a laboratory must obtain a certificate of registration to perform moderate or high complexity laboratory testing, or both, until the entity is determined to be in compliance through a survey by CMS. Id.

61. Each laboratory must be either CLIA-exempt or possess the applicable CLIA certification. 42 C.F.R. § 493.5(c).

B. Types of Urine Drug Tests

62. Urine drug testing is frequently used to determine the presence or absence of drugs.

63. In the clinical healthcare context, urine drug testing can be used to monitor whether patients are taking prescribed drugs, or taking or abusing drugs not prescribed.

64. Laboratory chemical analysis of urine specimens can be qualitative, which indicates whether a specific drug is present; semi-quantitative, which estimates the concentration of a specific drug; or quantitative, which indicates the actual concentration of a specific drug in the specimen.

65. Urine drug testing is often done in two stages: presumptive testing (sometimes referred to as "screening" testing) and, when necessary, definitive testing (sometimes referred to as "confirmatory" testing). First, the treating provider performs a presumptive test, which is typically qualitative or semi-quantitative. The presumptive test gives a positive result when the presence of a drug in the urine exceeds a given concentration and a negative result when the drug is below this concentration. A provider can then determine whether a second, definitive test, either qualitative or quantitative, is medically necessary.

66. The equipment required to perform definitive urine drug tests is more sophisticated, and providers typically refer definitive drug testing to independent laboratories.

67. Presumptive tests can be performed by an immunoassay analyzer, which is a device found in laboratories that rapidly determines the presence or absence of the tested drug. One such device is the Olympus AU 400.

68. To operate the Olympus AU 400, laboratories are required to obtain CLIA certification to perform moderate complexity laboratory tests.

69. If, after a moderate complexity presumptive test is performed using an Olympus AU 400, the provider determines that a definitive, high complexity test is necessary, the urine specimen can be sent to a second laboratory for more detailed confirmation testing.

C. Reimbursement for Laboratory Tests

70. Different types of urine drug tests have different costs.

71. During the time period relevant to the Complaint, Medicare generally reimbursed urine drug tests based on the methodology used by the laboratory or the complexity of the test.

72. Beginning in 2011, for initial urine drug screens using CLIA-waived tests or moderate complexity tests, providers could use HCPCS code G0434. This code was described by CMS as "Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter."

73. For urine drug tests using high complexity test methods, providers could use HCPCS code G0431. This code is described by CMS as "Drug screen, qualitative; multiple drug classes by **high complexity test method** (for example, immunoassay, enzyme assay) per patient encounter."

74. The phrase "multiple drug classes" refers to the fact that code G0431 is for a panel of drugs tested from the same urine sample. In other words, if a provider wanted to test a single urine sample for the presence of ten different types of drugs, then code G0431 would be billed once because it is inclusive of the entire panel of ten drugs tested from the single urine sample.

75. Published guidance from CMS in 2011 states that G0431 "will be used to report more complex testing methods, such as multi-channel chemistry analyzers, where a more complex instrumented device is required to perform some or all of the screening tests for the patient."

76. The CMS guidance also states, "This code may only be reported if the drug screen test(s) is classified as CLIA high complexity test(s)…."

77. The CMS guidance further states "CLIA moderate complexity tests should be reported under test code G0434…."

78. On average, Medicare reimbursed providers $97.10 per claim for HCPCS code G0431.

79. On average, Medicare reimbursed providers $19.44 per claim for HCPCS code G0434.

80. Beginning in 2016, CMS stopped utilizing HCPCS codes G0431 and G0434. At that time, CMS began using new HCPCS codes that were specific to either presumptive or definitive testing.

81. During the time period relevant to the Complaint, a healthcare provider could also perform a quantitative drug test of a confirmed drug to determine its concentration. For example, when several opioids were present in the urine of a patient prescribed a single opioid, quantification could help a healthcare provider discern whether the other opioids were derived from the prescribed opioid or whether the patient was consuming an opioid outside of the prescribed medication.

82. For a quantitative drug test, a healthcare provider could bill CPT codes in the ranges 80150-80299 and 82000-84999, such as 80154 for benzodiazepines, 82055 for alcohol/ethanol, 82145 for amphetamines, 82205 for barbiturates, 82520 for cocaine, 83840 for methadone, 83925 for opiates, 83992 for PCP, and 80299 for certain drugs not specifically enumerated by the CPT codes, such as oxycodone, ecstasy, and marijuana.

83. If a healthcare provider performed a urine drug test for the drugs covered by the 8-series codes listed above, it would be inappropriate for the provider to bill CMS using both code G0431

and the specific 8-series codes, because the quantitative tests for those same substances were included within code G0431.

84. To bill using both code G0431 and the 8-series codes would constitute "unbundling," which is when a provider bills for multiple procedure codes that are covered by a single code.

85. Unbundling services is prohibited by CMS and is considered by CMS to be fraudulent.

86. Beginning in 2015, CPT codes 80154, 82055, 82145, 82205, 82520, 83840, and 83925 were deleted and Medicare no longer reimbursed for these codes.

DEFENDANTS' FRAUDULENT SCHEME

I. Park Square Laboratory Could Not Perform High Complexity or Quantitative Tests.

87. At all times relevant to the Complaint, Park Square and its affiliates operated primary care and pain management practices at several locations in Rhode Island.

88. Park Square Laboratory performed laboratory tests on urine samples from patients at all of the Defendants' locations in Rhode Island.

89. Effective June 17, 2012, Park Square Laboratory received a CLIA Certificate of Waiver, meaning that it was certified to perform only tests that had been approved as CLIA-waived by CMS.

90. In late 2013 and early 2014, various employees of Park Square, including Dr. Shah, communicated with the Rhode Island Department of Health regarding seeking a certificate to perform both CLIA-waived testing and non-waived testing.

91. On January 28, 2014, Dr. Shah sent a fax to a Senior Clinical Laboratory Scientist with the Rhode Island Department of Health indicating that Park Square Laboratory was utilizing an Olympus AU 400.

92. In a CLIA application for a certificate of compliance, dated March 6, 2014 and signed by Dr. Shah, Park Square Laboratory sought a change in certificate in order to perform both CLIA-waived and non-waived testing.

93. The CLIA application form clearly stated, "Laboratory directors performing non-waived testing…must meet specific education, training and experience under…the CLIA requirements."

94. In an on-site state survey conducted on behalf of CMS on August 28, 2014, the surveyor noted that Park Square Laboratory had personnel qualified to conduct moderate complexity testing, but not high complexity testing.

95. At all times relevant to the Complaint, Park Square Laboratory has only used an Olympus AU 400 to perform urine drug testing.

96. At all times relevant to the Complaint, Park Square Laboratory has only used a moderate complexity testing method to perform urine drug testing.

97. At all times relevant to the Complaint, Park Square Laboratory has never had the equipment necessary to perform urine drug testing by high complexity methods.

98. At all times relevant to the Complaint, Park Square Laboratory has never employed an individual certified to perform urine drug testing by high complexity methods.

99. At all times relevant to the Complaint, Park Square Laboratory has never performed urine drug testing by high complexity test methods.

100. At all times relevant to the Complaint, in order to obtain high complexity urine drug test results, Park Square sent urine specimens of Park Square patients to independent laboratories that were capable of performing confirmatory testing.

101. For example, the equipment at Park Square Laboratory had the capability of determining whether oxycodone is present in a urine sample, but did not have the capability of comparing the levels of oxycodone, oxymorphone and noroxycodone in a urine sample.

102. In order to determine whether a patient who was being prescribed oxycodone was taking the medication as prescribed, Park Square Laboratory needed to send a urine sample to an independent laboratory for quantitative testing.

103. In approximately late 2014 or early 2015, at least one employee of Paramount Medical Billing discussed with Dr. Shah the fact that the Park Square Laboratory was only capable of performing moderate complexity testing.

104. In February 2017, a Park Square Laboratory employee sent an email to a Senior Clinical Laboratory Scientist from the Rhode Island Department of Health stating, "Dr. Shah wants to upgrade the lab from moderate to high complexity by bringing in LC/MS equipment. What is the process to change the status to high complexity in Rhode Island?"

105. The Department of Health employee responded that the "[laboratory] director will need to be requalified and have/qualify for Clinical consult/technical supervisor…."

106. The Park Square Laboratory employee responded, "Dr. Shah is also consulting a lab consultant who helped him set up this lab."

107. Park Square Laboratory never obtained equipment to perform high complexity urine drug testing.

II. Park Square Submitted Claims to Medicare and Medicaid for High Complexity and Quantitative Tests that Were Not Performed.

108. In spite of performing only moderate complexity urine drug screens for Medicare and Medicaid beneficiaries, Park Square and its affiliates submitted tens of thousands of claims to the

government stating that high complexity tests had been performed and seeking reimbursement for the same at the high complexity reimbursement rate.

109. For example, on September 2, 2014, patient B.A. was seen by Joseph Turner D.O. at Park Square's location at 73 Eddie Dowling Highway in North Smithfield (also known as Biltmore Medical)

110. The medical record from that visit indicates that B.A. was being prescribed oxycodone and that a urine drug screen should be performed. The medical record further states that the "Procedure Codes" should include "G0431 DRUG SCR QUAL; Multiple drugs." This record was signed by Joseph Turner, D.O.

111. The Park Square Laboratory record from B.A.'s September 2, 2014 visit, listing Dr. Zaheer Shah as the laboratory director, indicates that a urine drug screen panel was performed, showing a positive result for oxycodone.

112. The medical records for B.A. further indicate that the urine sample collected on September 2, 2014 needed to be sent to Renaissance Rx laboratory for high complexity confirmation testing, which the indicated specific concentrations of hydrocodone, oxycodone, noroxycodone, and oxymorphone.

113. On September 9, 2014, the Medicare Administrative Contractor for Rhode Island, National Government Services, Inc. ("NGS"), received a claim from Park Square Urgent Care, Inc. for Medicare beneficiary B.A.'s September 2, 2014 visit, which also identified Dr. Joseph Turner as the rendering provider of the service. This claim sought reimbursement from Medicare for high complexity HCPCS code G0431 for the urine drug screen performed at Park Square Laboratory, even though Park Square Laboratory could not perform high complexity testing and needed to send this beneficiary's urine specimen to an independent laboratory for

high complexity results. On September 23, 2014, Medicare paid Park Square Urgent Care, Inc. $97.22 for this claim.

114. On March 3, 2015, patient R.P. was seen by Joseph Turner, D.O. at the Park Square location at 73 Eddie Dowling Highway in North Smithfield.

115. The medical record from that visit indicates that R.P. was being prescribed oxycodone and that a urine drug screen should be performed. The medical record also states that the "Procedure Codes," should include "G0431 DRUG SCR QUAL; Multiple drugs." This record was signed by Joseph Turner, D.O.

116. The Park Square Laboratory record from R.P.'s March 3, 2015 visit, listing Dr. Zaheer Shah as the laboratory director, indicates that a urine drug screen panel was performed, showing a positive result for oxycodone.

117. The medical records for R.P. further indicate that the urine sample collected on March 3, 2015 needed to be sent to ACCU Reference Medical Lab for high complexity confirmation testing, which indicated the specific concentrations of oxazepam, oxycodone, oxymorphone, and noroxycodone in the urine specimen.

118. On March 12, 2015, NGS received a claim from Park Square Urgent Care, Inc. for Medicare beneficiary R.P.'s March 3, 2015 visit, which also identified Dr. Joseph Turner as the rendering provider of the service. This claim sought reimbursement from Medicare for high complexity HCPCS code G0431 for the urine drug screen performed at Park Square Laboratory, even though Park Square Laboratory could not perform high complexity testing and needed to send this beneficiary's urine specimen to an independent laboratory for high complexity results. On March 26, 2015, Medicare paid Park Square Urgent Care, Inc. $96.98 for this claim.

119. On August 14, 2015, patient S.H. was seen by Chi-Kuang Lai, M.D. at Park Square's location at 73 Eddie Dowling Highway in North Smithfield.

120. The medical record from that visit indicates that S.H. was being prescribed Subutex (containing buprenorphine) and that a urine drug screen should be performed. The medical record further states that the "Procedure Codes" should include "G0431 DRUG SCR QUAL; Multiple drugs." This record was signed by Chi-Kuang Lai, M.D.

121. The Park Square Laboratory record from S.H.'s August 14, 2015 visit, listing Dr. Zaheer Shah as the laboratory director, indicates that a urine drug screen panel was performed, showing negative results for all drugs tested, although some amounts of certain drugs had been detected, including buprenorphine.

122. The medical records for S.H. further indicate that the urine sample collected on August 14, 2015 needed to be sent to Highline Laboratory for high complexity confirmation testing, which the indicated specific concentrations of buprenorphine and nobuprenorphine in the urine specimen.

123. On August 17, 2015, NGS received a claim from Park Square Urgent Care, Inc. for Medicare beneficiary S.H.'s August 14, 2015 visit, which also identified Dr. Chi-Kuang Lai as the rendering provider of the service. This claim sought reimbursement from Medicare for high complexity HCPCS code G0431 for the urine drug screen performed at Park Square Laboratory, even though Park Square Laboratory could not perform high complexity testing and needed to send this beneficiary's urine specimen to an independent laboratory for high complexity results. On August 31, 2015, Medicare paid Park Square Urgent Care, Inc. $96.98 for this claim.

124. From March 5, 2014 to December 31, 2015, Park Square submitted approximately 14,335 claims for reimbursement by Medicare and Rhode Island Medicaid for urine drug testing using high complexity HCPCS code G0431.

125. Park Square received approximately $1,030,645.87 in reimbursement through Medicare and Rhode Island Medicaid for claims submitted under G0431 for this same time period.

126. Park Square and its affiliates also submitted additional claims to the government using CPT codes indicating that Park Square Laboratory had performed quantitative urine drug testing for Medicare and Medicaid beneficiaries.

127. For example, on May 16, 2014, patient M.M. was seen by Chi-Kuang Lai, M.D. at Park Square's location at 100 Smithfield Avenue in Pawtucket (also known as Advanced Urgent Care).

128. The medical record from the visit, signed by Chi-Kuang Lai, M.D., indicates that M.M. was being prescribed Suboxone and that a urine drug screen should be performed. The medical record further states that the "Procedure Codes" should include: 83925 Assay of Opiates, 80154 Benzodiazepines drug screen not elsewhere specified, 80299 Quantitative Assay, Drug oxycodone, 82055 Alcohol any specimen except breath, 82145 Amphetamine or methamphetamine, 82205 Barbiturates, not elsewhere specified, 82520 Assay of Cocaine, 83992 Assay for Phencyclidine, 83840 Methadone, 83925 Assay of Opiates buprenorphine, Modifiers: 91, and 80299 Quantitative Assay, Drug cannabinoids, Modifiers: 91.

129. The Park Square Laboratory record from M.M.'s May 16, 2014 visit, listing Dr. Zaheer Shah as the laboratory director, indicates that a urine drug screen panel was performed, showing a positive result for benzodiazepine, buprenorphine, and methadone.

130. On July 8, 2014, NGS received a claim from Park Square Urgent Care, Inc. for Medicare beneficiary M.M.'s May 16, 2014 visit, which also identified Dr. Chi-Kuang Lai as the rendering provider of the service. This claim sought reimbursement from Medicare for the eleven quantitative CPT codes listed above for the urine drug screen performed at Park Square Laboratory, even though Park Square Laboratory could not provide quantitative results. On September 4, 2014, Medicare paid Park Square Urgent Care, Inc. $26.50 for these claims.

131. From March 5, 2014 to November 28, 2014, Park Square submitted approximately 49,607 claims for reimbursement by Medicare and Rhode Island Medicaid for urine drug testing using the quantitative CPT codes 80154, 80299, 82055, 82145, 82205, 82520, 83840, 83925, and 83992. Park Square received approximately $535,708.29 in reimbursement through Medicare and Rhode Island Medicaid for claims submitted under CPT codes 80154, 80299, 82055, 82145, 82205, 82520, 83840, 83925, and 83992 for this same time period.

132. In total, Park Square submitted approximately 63,942 claims for reimbursement to Medicare and Rhode Island Medicaid for tests that it could not, and did not, perform.

133. Park Square received approximately $1,566,354.16 in reimbursement through Medicare and Rhode Island Medicaid for these claims.

134. The false information contained in Park Square's claims was material to the government's decision to pay Park Square's claims.

135. Dr. Shah, Park Square and its affiliates had actual knowledge, reckless disregard or deliberate ignorance of the fact that the Park Square Laboratory was only capable of performing moderate complexity testing and that Park Square Laboratory needed to send its urine samples to an independent laboratory in order to obtain high complexity confirmation testing.

136. Dr. Shah, Park Square and its affiliates had actual knowledge, reckless disregard or deliberate ignorance of the fact that the Park Square Laboratory was not capable of performing quantitative testing and that Park Square Laboratory needed to send its urine samples to an independent laboratory in order to obtain quantitative results.

137. Dr. Shah, Park Square and its affiliates had actual knowledge, reckless disregard or deliberate ignorance of the fact that Park Square was submitting claims to the government for the payment of high complexity and quantitative tests that it was not performing.

138. On August 28, 2018, Rhode Island Health Group, LLC purchased the non-medical assets of Park Square and PrimaCare.

139. Rhode Island Health Group, LLC purchased all right, title, and interest in Park Square's non-medical assets, including all laboratory equipment, all assignable contracts, and all transferable licenses, certifications, and approvals to do business, including any and all licenses and permits which are necessary for participation in the Medicare and Medicaid programs.

140. Rhode Island Health Group, LLC has received the benefit of the value of Park Square, which is based, in part, on claims submitted to the government prior to Rhode Island Health Group's acquisition of the non-medical assets of Park Square Laboratory.

141. Dr. Zaheer Shah is a part owner of Rhode Island Health Group, LLC, and at all times relevant to the Complaint had knowledge of Park Square Laboratory's testing methods and Park Square's billing practices.

FIRST CAUSE OF ACTION

(**False Claims Act: Presenting and Causing False Claims; 31 U.S.C. § 3729(a)(1)(A)**)

Park Square Urgent Care, Inc.; PrimaCare, Inc.; Biltmore Medical; Biltmore Medical A; Advanced Urgent Care; and Dr. Zaheer Shah

142. The United States re-alleges the preceding paragraphs as if fully set forth herein.

143. Defendants Park Square Urgent Care, Inc.; PrimaCare, Inc.; Biltmore Medical; Biltmore Medical A; Advanced Urgent Care; and Dr. Zaheer Shah knowingly presented, or caused to be presented, approximately 63,942 false and fraudulent claims to Medicare and Rhode Island Medicaid.

144. These claims were false, *inter alia*, insofar as they sought reimbursement for testing that Defendants either: (a) lacked the capacity to provide; (b) lacked the certification or qualifications to provide; or (c) otherwise did not perform at the level billed.

145. The false and fraudulent information in each claim was material to the government's decision to pay Defendants' false claims.

146. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

147. Defendants received approximately $1,566,354.16 in reimbursement through Medicare and Rhode Island Medicaid for false and fraudulent claims.

148. The United States sustained a loss from the Defendants' false and fraudulent claims.

149. Defendants are liable to the United States under the False Claims Act for three times the loss sustained by the United States; a civil penalty of not less than $5,500 and not more than $11,000 per false claim for violations occurring between September 28, 1999 and November 2, 2015 and a civil penalty of not less than $11,181 and not more than $22,363 per false claim for violations occurring after November 2, 2015; and the costs of this civil action brought to recover

such penalty and damages. 31 U.S.C. § 3729(a)(1), (3); Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461; 28 C.F.R. §§ 85.3(a)(9) (1999), 85.5.

SECOND CAUSE OF ACTION

(False Claims Act: False Record Material to False Claims; 31 U.S.C. § 3729(a)(1)(B))

Park Square Urgent Care, Inc.; PrimaCare, Inc.; Biltmore Medical; Biltmore Medical A; Advanced Urgent Care; and Dr. Zaheer Shah

150. The United States re-alleges the preceding paragraphs as if fully set forth herein.

151. Defendants Park Square Urgent Care, Inc.; PrimaCare, Inc.; Biltmore Medical; Biltmore Medical A; Advanced Urgent Care; and Dr. Zaheer Shah knowingly made, used, or caused to be made or used, false records or statements material to approximately 63,942 false or fraudulent claims to Medicare and Rhode Island Medicaid. Among other false records or statements, Defendants created medical records indicating that HCPCS and CPT codes for high complexity and quantitative laboratory testing should be submitted for payment and created, or caused to be created, health care insurance forms indicating that tests had been performed using high complexity and quantitative testing methods through the use of certain HCPCS and CPT codes.

152. These records or statements were false, *inter alia*, insofar as they indicated that Defendants had performed testing that Defendants either: (a) lacked the capacity to provide; (b) lacked the certification or qualifications to provide; or (c) otherwise did not perform at the level billed.

153. These false records or statements were material to the decision of the government to pay Defendants' false claims.

154. Defendants made, used, or caused to be made or used, said false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

155. Defendants received approximately $1,566,354.16 in reimbursement through Medicare and Rhode Island Medicaid for false and fraudulent claims resulting from the false records or statements that Defendants made, used, or caused to be made or used.

156. The United States sustained a loss from Defendants' false and fraudulent claims to Medicare and Medicaid resulting from the false records or statements that Defendants made, used, or caused to be made or used.

157. Defendants are liable to the United States under the False Claims Act for three times the loss sustained by the United States; a civil penalty of not less than $5,500 and not more than $11,000 per false claim for violations occurring between September 28, 1999 and November 2, 2015 and a civil penalty of not less than $11,181 and not more than $22,363 per false claim for violations occurring after November 2, 2015; and the costs of this civil action brought to recover such penalty and damages31 U.S.C. § 3729(a)(1), (3); Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461; 28 C.F.R. §§ 85.3(a)(9) (1999), 85.5.

THIRD CAUSE OF ACTION

(Payment by Mistake)

Park Square Urgent Care, Inc.; PrimaCare, Inc.; Biltmore Medical; Biltmore Medical A; Advanced Urgent Care; and Dr. Zaheer Shah

158. The United States re-alleges the preceding paragraphs as if fully set forth herein.

159. As consequence of the acts set forth above, the United States has paid money to the Defendants Park Square Urgent Care, Inc.; PrimaCare, Inc.; Biltmore Medical; Biltmore Medical A; Advanced Urgent Care; and Dr. Zaheer Shah because of mistaken understandings of fact.

160. The United States paid the Defendants for tens of thousands of urine drug test claims with the mistaken understanding that the Defendants had performed the tests by high complexity or quantitative methods, when in fact, they were not performed by high complexity or quantitative methods.

161. The United States' mistaken belief was material to its decision to pay Defendants' urine drug test claims.

162. Defendants are liable to account and pay to the United States the payments that the United States made in error.

FOURTH CAUSE OF ACTION

(Unjust Enrichment)

All Defendants

163. The United States re-alleges the preceding paragraphs as if fully set forth herein.

164. As a consequence of the acts set forth above, the Defendants have obtained funds, directly or indirectly, to which they were not entitled, and have been unjustly enriched.

165. The United States conferred benefits upon the Defendants, the Defendants knew of and appreciated these benefits, and the Defendants' retention of these benefits under the circumstances would be unjust as a result of their conduct.

166. The United States therefore claims the recovery of all monies by which the Defendants have been unjustly enriched, in an amount to be determined, which in equity should be paid to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants as follows:

I. On the First and Second Counts under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

II. On the Third and Fourth Counts for payment by mistake and unjust enrichment, for the damages sustained and/or amounts by which Defendants were unjustly enriched or were paid by

mistake, or by which Defendants retained illegally-obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

III. Pre-and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Dated: March 5, 2020

UNITED STATES OF AMERICA

By Its Attorneys,

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